CONCISE EXPLANATORY STATEMENT
WAC 246-919-605 and WAC 246-918-125
"Use of Lasers, Light, Radiofrequency, and Plasma Devices as Applied to the Skin."
Effective March 1, 2007

On August 25, 2006, the Medical Quality Assurance Commission (Commission) adopted WAC 246-919-605 and WAC 246-918-125 "Use of Lasers, Light, Radiofrequency, and Plasma Devices as applied to the Skin." The rules will become effective on March 1, 2007.

The Commission was concerned that unlicensed or inadequately trained persons were using prescriptive devices on patients. In response to this in 2003, the Commission created a policy entitled, "The Use of Lasers in Skin Care and Treatment." Since the adoption of the policy, the Department of Health (The Department) has continued to receive several unlicensed practice and patient harm complaints regarding Lasers, Light, Radiofrequency and Plasma devices (LLRP). In addition, numerous non-laser devices have entered the market and the number of inquiries about the use of lasers and similar devices has increased since the policy took effect.

The Commission believes when used appropriately, these instruments are generally safe and relatively easy to operate. But the potential for patient injury with untrained, inappropriate, or negligent operation is significant. The Commission also believes that it is necessary to clarify this area of medicine and set minimal standards for the use of such devices by physician and physician assistants.

The adopted rules define LLRP devices, specify who can operate a device and under what circumstances, who can delegate the use of a devices and under what circumstances, and the degree of supervision required after delegation.

The adopted rule is not different from the text of the proposed rule. However, in response to the feedback from the public and constituents, the Commission has elected to delay the effective date until March 1, 2007. This will give users of LLRP devices time to comply with the rule

The following is the summary of comments received and the Commission's responses.

PUBLIC COMMENT	COMMISSION'S RESPONSES
LASER EQUIPMENT	
The Commission should modify the rules and accordingly "use of medical devices using any form of energy to penetrate or alter human tissue for a purpose…" should be eliminated.	The Commission stated that the legislature has defined the penetration of human tissue as the practice of medicine. (See RCW 18.71.011(3)). The adopted rules only pertain to prescriptive devices.
The Commission should recognize and identify the significant risk variables based on the actual laser,	While there is variability in lasers, the Commission is only interested in prescriptive

for example the risk factors for an IPL are much greater that of an Alexandrite laser with cooling.	devices as defined by the Food and Drug Administration. The Commission is relying on the FDA's definition of prescriptive devices.
The commenter stated that the proposed rules should use the FDA regulations CFR 21 1040.40 which defines lasers instead of the unnecessary and restrictive language being proposed by DOH rules.	The Commission stated the rules pertain to LLRP devices defined by the FDA as prescriptive devices not the class of lasers. The Commission stated that the LLRP devices is a rapidly changing field and felt it would not be of benefit to use the classification of lasers because the FDA classification system is related to potential eye injury
The Commission should not use the term radiofrequency in the proposed rules because such board language could eventually be construed to include electrolysis. If the Commission is trying to regulate "thermage", then say it that way. If Commission's intent is to draft a language broad enough to cover future technologies, then at least specifically exclude electrolysis from this type of over regulation.	The Commission reported that during the rules process, many physicians (MD) expressed the desire to have radiofrequency specifically addressed in rules. The Commission stated that the term "Radiofrequency" is the correct term of which Thermage is only one type of radiofrequency procedure. The Commission also stated that the adopted rules do not include electrolysis, provided the electrologist is not using prescriptive LLRP devices.
How do unlicensed folks or clinics get prescriptive lasers?	Many purchases are made through second-hand market or inappropriate purchasing from the internet.
NON-PHYSICIANS	
The Commission should allow the MD to delegate licensed or certified non-physician practitioners. Consider the DRAFT statement of the American College of Surgeons.	The Commission stated the recommendations from the American College of Surgeons "Draft Statement on Surgery Using Lasers, Pulsed Light or Radiofrequency Devices or Other Techniques" states devices "**may be delegated to non-physician advanced health practitioners who are appropriately trained and licensed by the state in which they practice."** The adopted rule WAC 246-919-605 (10) states "may delegate to a properly trained and licensed professional, whose licensure and scope of practice allow the use of an LLRP device"… The Commission believes the adopted rules are less restrictive than the draft guidelines.
The Commission should allow the non-physician practitioner to evaluate and treat patients under the guidelines of a written protocol.	The Commission believes that evaluating and treating patients is the practice of medicine as stated in RCW 18.71.011 "a person is practicing medicine if he or she does one or more of the following: (1) Offers or undertakes to diagnose, cure, advise, prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;..." and

	must be licensed to do so.
The Commission was told that was a shame to see regulations that limit some of the most qualified "paramedical professionals" from doing a job that they are highly trained to perform and turn it over to individuals less experienced and trained.	The Commission reported that a "Paramedical Professional" is not a specific category of health care provider licensed in Washington and therefore should not be practicing medicine in the state of Washington. The Commission stated the adopted rules require individuals to be licensed and whose scope of practice allows for LLRP devices.
The Commission was told that aging skin and normal hair growth is not classified as a "physical ailment, physical injury or deformity." Therefore beauty treatment to reduce the appearance of aging and normal hair growth should not be considered medical treatments subject to the rules governing the practice of medicine.	The Commission stated the rules apply to LLRP devices defined by the FDA as prescriptive devices that penetrate the human tissue which is considered the practice of medicine. The Commission is concerned about the potential for harm the Commission from the use of the LLRP devices.
The Commission should allow a physician to delegate to licensed or certified non-physician practitioners.	e Commission stated the adopted rules allow physicians to delegate to licensed professionals. WAC 246-919-605 (10) states "may delegate to a properly trained and licensed professional, whose licensure and scope of practice allow the use of an LLRP device"…
ESTHETICIANS	
The Department of Licensing requested that the rules be postponed.	The Commission reported the Department of Health has kept the Department of Licensing continually informed during the two-year rules process of every draft. The Commission stated DOH and Department of Licensing (DOL) staff have been in on-going discussions on the latest draft of the adopted rules before the filing.
The Commission was asked if licensed aestheticians specializing in laser hair removal were notified of the proposed rule making process. Another complained they were not notified of the proposed rules.	The Commission stated they kept the DOL Cosmetology Board have been informed from the beginning and throughout the rules process. Melissa Burke-Cain, AAG, reported the Commission has met all requirements in the notification of the rules. The Commission also stated the rules were properly posted with the Code Revisers Office giving proper notice of the hearing and the process for submission of written comments
The Commission was asked to keep the estheticians doing what they do best--Laser Hair removal. An aesthetician has to spend 600 hours learning that they are taking care of an individual's skin, which includes the ability to know when to turn a client over to a MD or PA for treatment.	The Commission stated DOL determines scope of practice and training requirements of estheticians. The Commission stated the adopted rules do not exclude licensed estheticians if the use of LLRP is within their scope of practice, but they must be appropriate trained and supervised by a physician or physician assistant.

The Commission was asked if an esthetician can perform "Thermage" under a physician's supervision.	The Commission stated that thermage is a type of radiofrequency and is therefore covered by the rules. Thermage penetrates and alters human tissue and is, therefore, the practice of medicine. Many physicians submitted comments during the rules process stating it was important to add radiofrequency devices to the devices covered by rules.
The proposed rules are too broad in definition and include non-invasive, purely cosmetic procedures, such a laser hair removal within the practice of medicine when such procedures are more logically and appropriately described as aesthetic practice.	The Commission stated that legislature has defined the penetration of human tissue as the practice of medicine. RCW 18.71.011(3). The adopted rules only pertain to prescriptive devices. The Commission stated that the Washington State Medical Association representing MDs was active throughout the entire rules process, and supports the rules as written. Physicians from many specialties commented on multiple draft rules during the development of the proposed rules; some specialties consider the proposed rules to liberal while others believe they were too restrictive.
The Commission was told that if an esthetician sees a change in the skin the esthetician always send them to the doctor.	The Commission indicated that estheticians have not been adequately trained or licensed to practice medicine in the diagnosis of the skin or other conditions requiring a consultation with a MD or PA.
The Commission should require everyone who is treating a person for hair removal with lasers should be certified including MDs, PAs and nurses. The rules should be about training, not about the type of medical degree.	The Commission stated the adopted rules require MDs and PAs and those they delegate to must have appropriate LLRP training in order to use and delegate the use of the LLRP prescriptive devices.
LASER TECHNICIANS	
The Commission should create a new license or give current laser technicians a test to see if they are truly qualified.	The Commission has no authority to create a professional license; however, there is a legislative sunrise process to create a new type of licensure. In addition, the Commission does not have authority to give examination for other professions without first having legislative authority.
The Commission was asked to keep Laser Technicians because Laser technicians went to an accredited school they are qualified to continue with their career. Some of the laser technicians are a licensed as an electrologist in California. The Commission did not consider laser technicians, were not included under "licensed professionals in your proposal."	The Commission stated Laser Technicians are not licensed by Department of Health or the Department of Licensing. The Commission indicated that laser technicians should not be practicing medicine by using the prescriptive LLRP devices without a license. In order for laser technicians to become licensed, they would need to go through a legislative sunrise process to create licensure that allows them to use the LLRP

	devices. The Commission further added that MDs and PAs cannot delegate prescriptive laser functions to anyone who is not licensed or to anyone with ascope of practice that does not include the use of prescription devices The MD or PA could be charged with aiding and abetting unlicensed practice. The non licensed person could be issued a cease and desist to stop practice. The Commission stated that electrologists do not have a license in this state; however they are exempt by the Department of Licensing as long as they are not using a prescriptive laser device.
STATISTICAL DATA	
The Commission has not offered any statistical information to back up their claims that there is a need for the rules The proposed regulations are overly burdensome requirements which are not tailored to improve any reported health risk.	There is no statistical data, only anecdotal evidence to support the Commission's reason for adoption of the rules. The Commission feels that the following examples provide good reason to set minimal standards: o There has been a case of a young lady who had a spot removed by a laser; unfortunately the spot was a malignant melanoma. o There are seven known cases of patient complaints to Department of Health's (DOH) Unlicensed Practice Unit for unlicensed use of lasers in which cease and desist orders were issued. o In addition to the seven cases for which cease and desist orders were issued, eight more cases of patient complaints were submitted to DOH unlicensed practice. These cases are currently under investigation. o In 1995 there was a case against a physician where inappropriate delegation to staff resulted in a patient being burned. The case resulted in disciplinary action. o The Commission has received complaint cases of facial and leg burns. In addition, the Commission has researched the experience of other states regulatory approaches for additional supportive data. Data used from the "Use of Laser and Delegation of Medical Functions Regulation by State" from the Federation of State Medical Boards.
<u>OTHER PROFESSIONALS</u>	
The Commission was asked if a "company educated staff" can perform the LLRP procedures.	The Commission stated only a licensed professional whose scope of practice includes the ability to perform LLRP procedures may use LLRP devices.

The Commission received a comment from an LPN and an owner of a medical spa who indicated that they have an off-site medical director who oversees their medical process and uses certified nurses to perform the laser treatments. The Commission should have guidelines and accountability for laser treatments but this is not the direction it should be going.	The Commission's adopted rules only cover those lasers that are defined by the FDA as prescriptive devices. The rules address what is appropriate supervision. The Commission stated the use of LLRP prescriptive devices lasers are not within the scope of practice of a certified nurse assistant. The delegation by an LPN and running a medical spa should be addressed by the Nursing Quality Assurance Commission.
The Commission was asked why a nurse or dental hygienist could use a laser and not have certification.	The Commission reported the adopted rules regulate only physicians and physician assistants. They indicated a nurse's scope of practice is determined by the Nursing Commission and the Commission understands that nurses are allowed to use lasers according to scope of practice according to a position statement dated November 7, 2003. Dental hygienists are only allowed to use lasers in their scope of practice under the supervision of a dentist.
The Commission was asked to regulate the training, set higher standards, but allow physicians the ability to decide who they feel is most qualified to perform a treatment when it is their license on the line.	The Commission stated that MDs are required to appropriately supervise auxiliary staff, according to RCW 18.130.180 (14) it is unprofessional conduct not to adequately supervised auxiliary staff. MDs and PA are to delegate only to those who are licensed to perform those procedures using the LLRP devices.
Can and ND be a medical director or use the LLRP devices under a MDs supervision?	The Commission stated that according to RCW 18.36A.020 (8), Naturopathic Physician (ND) is allowed to use physical, chemical, electrical or other non-invasive modalities, including, but not limited to heat, cold, air, light, water in any of its forms sound, massage, and therapeutic exercise. The LLRP prescriptive devices are considered invasive modalities that penetrate human tissue. Therefore, NDs may not be a medical director or be supervised by a MD or PA. For more information on the scope of practice for a naturopathic physician, contact the Department of Health Naturopathic Committee's Program Manager Sue Gragg at 360-236-4941.
The Commission was requested to add the ARNPs and RNs to the rule language	The Commission indicated they cannot write rules for other professions. ARNP have independent prescriptive authority and can use the LLRP devices without supervision or delegation of an MD; however according to the position statement by the Nursing Commission dated 11/7/03, RNs and LPNs must have appropriate supervision by a MD or PA to use the LLRP devices.

CONCISE EXPLANATORY STATEMENT
WAC 246-919-605 and WAC 246-918-125

PATIENT EXAMINATION	
The Commission was asked if there is added value of having a MD or PA doing an examination on every patient. Treatments should be more clearly outlined. Is the MD or PA's credentialing a guarantee of a better outcome?	The Commission considers a history and examination of all patients to be standard of care before any diagnosis or treatment plan begins. The Commission stated their highest priority is to protect the public. The Commission agrees that there is no guarantee of a better outcome; however the FDA labels certain lasers as prescriptive devices for a reason, thus ensuring that minimal safeguards are in place for the use of such devices
The Commission was told that the medical field (doctors and nurses) cannot handle the additional volume of patients who have either voluntarily elect to have these procedures or find it medically necessary.	The Commission stated that generally hair removal is not considered medically necessary, and the rules do not impact medically necessary patient care. The Commission further stated that access to care, in of itself, is not a basis for abdicating the practice of medicine. Typically, medically necessary procedures using LLRP devices are ablative.
ON-SITE SUPERVISION	
The Commission was asked if the physician can be on-call for 24 hours instead of being on site The Commission was also asked if the rules require on-site by the physician but not direct MD supervision	The Commission stated this is a public safety issue and that appropriate supervision will provide for prompt treatment when complications arise. The adopted rules require immediate supervision on the premises only during the patient's initial treatment. The Commission reported the rules clearly define appropriate supervision of licensed professionals using LLRP devices as follows: o For PAs, the supervisor is to be on the "immediate premises" at all times. o For MDs, they are required to be on the immediate premises during the initial treatment of a treatment plan that the MD has laid out. o If the supervising MD is called away for an emergency during a patient's initial treatment, the rules provide for that licensed professional to be able to go ahead and complete the treatment. o For subsequent treatments of the treatment plan, the licensed professional may perform the treatments during "temporary absences" of the MD, so long as there is a back-up MD available by phone and accessible (to see the patient) within 60 minutes. The Commission stated it is standard of care for the MD or PA role to provide the patients with an initial history, perform an appropriate physical examination,

	make an appropriate diagnosis and recommend appropriate treatment, and obtain an informed consent (including that the treatment will be performed by a non-physician). The MD or PA will be held ultimately responsible for the treatment of the patient. The Commission stated that any quality assurance protocols need to include a mechanism to identify complications, adherence of supervised written protocols, and monitoring the quality of treatments.
The Commission was asked if someone really needs to be physically on the premises and why is a PA required to be on site every minute the device is used and that it is unnecessary to have a PA to be on-site at all times.	The Commission believes that the adopted rules as written are the best guarantee for patient safety. PAs are licensed as a "dependent practitioner", and believes at this time PAs need closer monitoring of those to whom the PA delegates LLRP procedures. The Commission believes it is the responsibility of the physician to ensure the patient safety. MDs supervise and delegate to PAs and the Commission believes that responsibility should not be delegated again. The Commission stated it is rational for a PA to be on site because the Pa is delegating to another professional.
TRAINING	
The Commission should require Laser Certification and should require continuing laser education for all practitioners. Another comment indicated that the proof of education should be displayed.	The Commission stated that the adopted rules do require specific training by MDs and PAs. WAC 246-919-(4) and WAC 246-918-125(4) require both MD and PA to be appropriately trained in the physics, safety and techniques of using LLRP devices prior to using such devices and must remain competent for as long as the device is used. The Commission indicated if the suggestion was for a new "laser certification" for all practitioners, it would require a legislation sunrise review. The adopted rules also require on-going competency for as long as the device is used. The Commission stated they have not asked anyone to display a proof of education
The Commission was told that training and certification is more important than having a MD or PA on-site. Historically, most adverse events have been physician responsibility. The Commission was asked why are MDs and PAs more qualified to use the laser or do they have any training on the use of lasers? The Commission was told that the proposed rules do not address the true issue, which is the training of the individual operating the laser and the protocol that is followed.	The Commission reported the adopted rules do require the MD & PA and delegated individuals to have training. MD and PA basic medical training includes skin lesions and other skin conditions. The training in use of LLRP devices should be more than just technical but should include with the condition of the skin. The rules do not detail training because it changes with the types of lasers. However, there must be on-going training that coincides with the changes of lasers. WAC 246-919-(4) and WAC 246-918-125(4) require both the MD and PA to be appropriately trained in the physics, safety and techniques of using LLRP devices

	prior to using such devices and must remain competent for as long as the device is used. DOL sets training requirements for estheticians.
GRANDFATHERING	
The Commission was asked to allow for time to comply or possibility of grandfathering in the many small clinics involved.	The Commission stated the adopted rules effective date is March 1, 2007. This provides opportunity for more coordination with Department of Licensing and compliance with the adopted rule.
The Commission was told that at minimum, licensed estheticians who have years of experience and training should be grandfathered into these new policies so they are able to provide the care and services that they have provided for many years. Experience can often be a much more valuable tool than having an advanced medical degree	The Commission reported the adopted rules do not disallow estheticians from using the lasers if it is within their scope of practice and under a MD or PA supervision. DOL determines the scope of practice for estheticians.
The Commission was asked to grandfather in MA's, Nurses and estheticians by allowing a 6-9 month grace period to acquire the required laser certification.	The Commission stated the adopted rules have an extended effective date of March 1, 2007 to give more time for compliance. The Commission also reported Medical Assistants are not licensed by the state, and therefore may not use the LLRP devices; Licensed Health Care Assistants are licensed, but LLRP devices are not within their scope of practice; Nurses –ARNP have independent prescriptive authority and therefore may use the LLRP devices because it is within their scope; RN &LPN are allowed to use the LLRP devices as long as they are under appropriate supervision; and estheticians are not specifically excluded by the proposed rules, but DOL defines their scope of practice
ECONOMIC BARRIERS	
The Commission should not adopt the proposed regulation regarding lasers in this state.	The Commission stated it has a responsibility to protect the public from unlicensed or inappropriate delegation of the practice of medicine and that physician or physician assistants have a significant responsibility in the delegations of those using a prescriptive device.
The Commission's Small Business impact (SBEIS) is understated.	The Commission stated it will have staff review the Small Business Impact Statement and revise if necessary.

CONCISE EXPLANATORY STATEMENT
WAC 246-919-605 and WAC 246-918-125

The Commission was asked if there is any opportunity to stay the enforcement of the new rule until current licensed holders have a chance to figure out how to support themselves and their families?	The Commission stated it has been working on the rules since 2004 and in order to help give individuals more time to prepare the rules will not go into effect until March 1, 2007. The Commission stated that if an unlicensed individual is practicing medicine without a license, the current statute prevails and they must stop practicing immediately.
The Commission was told that the proposed rules will cause an unnecessary rise in economic barriers due to competition in the cosmetic service industries. It was reported that 50% of the laser clinics in Puget Sound area do not fit in the new ruling because of utilizing unlicensed laser technicians and will have to replace their staff or shut down. In addition, the proposed rules causes "Restrictive Commerce" and the cost to the consumer will be driven out of reach, except for the most privileged.	The Commission reported the role of the Medical Commission is to focus on public safety and the practice of medicine in Washington State. In that role, it is concerned about inappropriate and unlicensed individuals use of prescriptive LLRP devices either on their own or under inappropriate supervision by a MD (such as a MD allows his or her name to be used a medical director and not be present). The Commission stated the rules actually allow a broader legal use of prescriptive devices. In addition, patient safety is of higher interest to the Commission than economic concerns.
The Commission should understand that patients are prescribed medical devices all the time by physicians.	The Commission stated that prescribing the use of medical devices to patients is a common practice in medicine but only after the MD or PA has completed the history and made a diagnosis and monitors the use of medical devices.